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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/651,307	08/28/2003	Chia-Gee Wang	U 014776-3	9029

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LADAS & PARRY LLP
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NEW YORK, NY 10023

EXAMINER

HUGHES, ALICIA R

ART UNIT	PAPER NUMBER
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1614

MAIL DATE	DELIVERY MODE
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12/09/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/651,307	Applicant(s) WANG ET AL.	
	Examiner ALICIA R. HUGHES	Art Unit 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 August 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 115, 122 and 124-147 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 115, 122, and 124-147 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the Claims

Claims 115, 122 and 124-147 are pending, and the subject of this Office Action.

Applicants' arguments, filed on 21 August 2008 have been fully considered and are deemed to be persuasive regarding previous rejection.

Rejections and objections not reiterated from previous office actions are hereby withdrawn. Unfortunately, upon reconsideration of the pending claims, as presented, the following new rejections are applied. They constitute the complete set of rejections being applied to the instant application presently.

Claim Rejections - 35 U.S.C. §112.1

The following is a quotation of the first paragraph of 35 U.S.C. §112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 115 and 122 and 124-147 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Art Unit: 1614

Applicant, in its Remarks filed on 29 February 2008, amended claim 115, incorporating the language:

preferential destruction [sic] of tumor cells ... such that the rose bengal accumulates in lysosomes of cells of the subject ... with an x-ray tube that emits monochromatic line emission x-rays having an energy above and near the K-absorption edge or the L-absorption edge of iodine that is present in the rose bengal ... said irradiating being confined to the specific location comprising the tumor so as to localize damage caused by the irradiating and to minimize damage to normal cells of the subject.

However, the amendment changed the scope of the invention by adding to the language “such that rose Bengal accumulates in lysosomes wherein the cells comprise lysosomes in which rose bengal accumulates ...”

A review of application as filed does not disclose the invention embodied by the present set of claims. In addition to what is referenced herein, *supra*, a review of the application and present claims has determined a discrepancy regarding to what the dosage is directed compared to what the dosage was directed previously. Previously, there was no selected region in the subject for receipt of the dosage whereas now the lysosomes are the selected region, and this is not supported by the specification. And if the same is supported, Applicant has failed to draw attention to the page and line numbers in the specification that support its amendment.

In light of the foregoing and absent any express evidence to the contrary, claims 115 and 122 and 124-147 are rejected, because they contain new matter not supported by the specification. This is a new matter rejection.

Art Unit: 1614

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office Action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 115 and 122 and 124-147 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,366,801 B1 [hereinafter referred to as “Cash et al”] in view of U.S. Patent No. 5,627,871 [hereinafter referred to as “Wang”] and Ariel et al, “Treatment of Inoperable Cancer of the Liver by Intra-Arterial Radioactive Isotopes and Chemotherapy,” *Cancer*, Vol. 20, No. 5, pages 793-804 (1967)[hereinafter referred to as Ariel et al”].¹

The teachings of Cash et al, Wang, and Ariel et al from this Office’s action of 08 May 2006 and 28 August 2007 and all arguments emanating therefrom, are incorporated herein by reference, in total.

¹ Cited on the PTO-892 form filed on 08 May 2006.

Art Unit: 1614

It is important to note that the radioactive iodine rose bengal disclosed in Ariel et al is reasonably acceptable as a type of rose bengal to those of skill in the art. And furthermore, the line emission X-ray treatment as set forth in the previous Office Action by way of Cash et al in view of Wang reasonably suggests that the irradiation of iodine within the rose bengal compound type, thereby providing tumor treatment, as claimed in the present invention.

In light of the disclosures, one of ordinary skill in the art would be motivated to utilize rose bengal as an anti-therapeutic agent to treat cancerous tumors. Thus, the combined references teach and make *prima facie* obvious how to use the claimed invention at the time that it was made.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alicia Hughes whose telephone number is 571-272-6026. The examiner can normally be reached from 9:00 A.M. until 5:00 P.M. on Monday through Friday.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

Art Unit: 1614

CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, can be reached at 571-272-0718. The fax number for the organization where this application is proceeding is assigned 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Alicia R. Hughes/
Examiner, Art Unit 1614

/Raymond J Henley III/
Primary Examiner, Art Unit 1614